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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/496,444 02/02/00 TAO

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EXAMINER

COLLINS, C

ART UNIT

PAPER NUMBER

1638

12

DATE MAILED:

09/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Offic Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/496,444	TAO ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Cynthia Collins	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period f r Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 03 July 2001.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disp sition of Claims**

4) Claim(s) 2-18,22-25,27-53 and 64 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 2-18, 22-25, 27-53 and 64 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

1. The Amendment filed July 3, 2001, paper no.11, has been entered.
2. Claims 1, 19, 20, 21, 26, and 54-63 have been cancelled.
3. Claim 64 has been newly added.
4. Claims 2, 4, 6-11, 13, 18, 22, and 23 have been newly amended.
5. Claims 2-18, 22-25, 27-53, and 64 are pending.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Information Disclosure Statement***

7. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 8, is attached to the instant Office action.

#### ***Claim Objections***

8. The objection to claim 1 is withdrawn in light of Applicant's cancellation of claim 1.

#### ***Claim Rejections - 35 USC § 112***

9. Original claims 3, 5, 12, and 14-17 remain rejected, newly added claim 64 is rejected, and newly amended claims 2, 4, 6-11, 13, 18, and 22 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous office action.
10. Applicant argues that the cancellation of claim 1 and its replacement with newly added claim 64 overcomes the rejection by deleting references to a polynucleotide amplified from a

plant nucleic acid library, references to a polynucleotide having 20 contiguous bases of SEQ ID NO:1, references to a polynucleotide encoding a plant Cyclin E protein, and references to a plant Cyclin E polynucleotide that hybridizes under stringent conditions to SEQ ID NO:1. Applicant also argues that support for the description of structure and function are provided to the claim requirements by the limitation "CycE nucleic acid", which is defined in the specification as encoding a polypeptide that binds to Cdk2, has a cyclin box, and contains the conserved motif TTPXS. Applicant additionally argues that the function, utility, and effect of incorporating CycE nucleic acids into a cell or plant is disclosed in the specification as an expected improvement in transformation efficiency. Applicant further argues that their 1.132 Declaration provides evidence that SEQ ID NO:1 exhibits the structure and function of a CycE polynucleotide.

11. In general, Applicant's 1.132 Declaration asserts that the structural and functional distinctions used to classify mammalian cyclins can be used to verify that the present inventive polynucleotides and proteins are Cyclin-E polynucleotides and proteins.

12. Specifically, the Declaration asserts that the inventive polynucleotide encodes a cyclin because the protein encoded by the inventive polynucleotide contains the highly conserved amino acid consensus sequence known as the cyclin box that is characteristic of cyclins. The Declaration also asserts that the inventive polynucleotide encodes a functional cyclin because the inventive polynucleotide has the ability to complement G1-cyclin-deficient yeast, a function that is characteristic of D-type and E-type cyclins only. The Declaration further asserts that the inventive polynucleotide encodes a functional E-type cyclin because the protein it encodes lacks the highly conserved Rb-binding motif LxCxE that is characteristic of D-type cyclins, and

because the protein it encodes contains a carboxy-terminal CDK2 phosphorylation site (TPPXS) that is characteristic of E-type cyclins.

13. Applicant's arguments have been fully considered but are not persuasive.
14. The Examiner maintains that the invention was not adequately described. Although a nucleic acid comprising a polynucleotide encoding SEQ ID NO:2 and a polynucleotide comprising SEQ ID NO:1, and complementary nucleotides thereof are adequately described, a nucleic acid comprising a CycE polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1 and complementary nucleotides thereof are not adequately described. It is unclear how the cyclin box and TPPXS structural elements of a CycE polynucleotide relate to its function, or whether the structure and function of those elements would be preserved in an isolated nucleic acid having at least 80% identity to the entire coding region of SEQ ID NO:1. Likewise, it is unclear whether an isolated nucleic acid having at least 80% identity to the entire coding region of SEQ ID NO:1 would encode a polypeptide that binds to Cdk2. One skilled in the art could not predict the structure and function of isolated nucleic acids comprising a CycE polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1 and complementary nucleotides thereof.
15. Original claims 3, 5, 12, 14-17, 24-25, and 27-53 remain rejected, newly added claim 64 is rejected, and newly amended claims 2, 4, 6-11, 13, 18, 22, and 23 are rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

16. Applicant argues that their 1.132 Declaration provides evidence that SEQ ID NO:1 exhibits the structure and function of a CycE polynucleotide. Applicant also argues that the function, utility, and effect of incorporating CycE nucleic acids into a cell or plant is disclosed in the specification as an expected increase in the G1 to S transition, and an expected increase in transformation efficiency. Applicant further argues that their 1.132 Declaration provides evidence that SEQ ID NO:1 exhibits the structure and function of a CycE polynucleotide. Applicant additionally argues that claim 64 is to a CycE nucleic acid, which is defined in the specification as encoding a polypeptide that binds to Cdk2, has a cyclin box, and contains the conserved motif TTPXS.

17. Applicant's arguments have been fully considered but are not persuasive.

18. The Examiner maintains that the scope of the invention is not enabled. Although Applicant's 1.132 Declaration does provide evidence that the specification is enabled for an isolated CycE nucleic acid comprising a polynucleotide encoding SEQ ID NO:2, and a polynucleotide comprising SEQ ID NO:1, and complementary nucleotides thereof, the specification does not reasonably provide enablement for a CycE polynucleotide having at least 80% identity to the entire coding region of SEQ ID NO:1 and complementary nucleotides thereof. The scope of the invention is not enabled because of the unpredictability of determining the function of isolated nucleic acids homologous to SEQ ID NO:1, and because of the unpredictability of altering the phenotype of a plant by transforming it with isolated nucleic acids homologous to SEQ ID NO:1.

***Claim Rejections - 35 USC § 101***

19. Original claims 3, 5, 12, and 14-17 remain rejected, newly added claim 64 is rejected, and newly amended claims 2, 4, 6-11, 13, 18, and 22 are rejected under 35 U.S.C. 101 as not being supported by a specific and substantial utility, for the reasons of record set forth in the previous office action.
20. Applicant argues that the function, utility, and effect of incorporating CycE nucleic acids into a cell or plant is disclosed in the specification as an expected increase in the G1 to S transition, and an expected increase in transformation efficiency.
21. Applicant's arguments have been fully considered but are not persuasive.
22. The Examiner maintains that the invention does not have a specific and substantial utility because it is unclear whether the expression of a functional CycE nucleic acid in a host cell would result in an increase in the G1 to S transition of the host cell, or an increase in transformation efficiency of the host cell.
23. The rejection of claims 18 and 19 under 35 U.S.C. 101 as being directed to non-statutory subject matter is withdrawn in light of Applicant's amendment of claim 18 and cancellation of claim 19.

***Claim Rejections - 35 USC § 102***

24. The rejection of claims 1-12 under 35 U.S.C. 102(b) as being anticipated by Kende et al. is withdrawn in view of Applicant's cancellation of claim 1.

***Conclusion***

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
September 13, 2001

ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600  
